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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,003	09/11/2003	Se-Jin Lee	JHU1410-1	8520

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EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,003	LEE ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 25-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 25-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Restriction requirement supersedes the Restriction requirement previously made.

During the telephone conversation with Ms. Haile, it was made apparent that the previous restriction requirement had not considered the preliminary amendment received on September 11, 2003. It was agreed that a supplemental restriction requirement would be mailed, resetting the response time period.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 25-50 and 53-65, drawn to a method of detecting a target myostatin variant nucleic acid and a kit comprising the amplification primers and hybridization probes, classified in class 435, subclass 6. This Group is subject to further *species **and** restriction requirement.*

II. Claim 51, drawn to a kit comprising an antibody specific for a variant myostatin polypeptide, wherein said antibody is specific for amino acid residues 1-273 of a wild-type myostatin polypeptide, classified in class 435, subclass 387.1.

III. Claim 52, drawn to a kit comprising an antibody specific for a variant myostatin polypeptide, wherein said antibody is specific for amino acid residues 274-375 of wild-type myostatin polypeptide, classified in class 435, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are each unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions have different structures and are useful for different purposes. For example, the invention of Group I is drawn to a method and kit involving nucleic acids and thus involves structurally different elements, *i.e.,* nucleic acids, involving different mode of operation, *i.e.,* hybridization, whereas the inventions of Groups II and III are drawn to polypeptide and antibody recognition.

The invention of Group II is different and unrelated to Group III because the antibody comprised by the inventions are structurally and functionally different in that they are specific for non-overlapping regions of a protein. It is well-known in the art that the function of a protein is intimately related to its structures, and therefore, it is determined that the structure of an antibody specific for a particular region of a protein is different from the structure of an antibody that is specific for a particular region of a protein wherein said region is non-overlapping, resulting in searches and examination which are non-overlapping nor co-extensive in scope.

Further Species requirement for Group I

This application contains claims directed to the following patentably distinct species of the claimed invention:

A – Types of different variance

i) mutation (claim 28);

ii) RFLP (claim 28);

iii) nucleic acid deletion (claim 28 and 29);

iv) nucleic acid substitution (claim 28 and 30);

B – sample types

i) avian (claim 36, 38, and 39);

ii) bovine (claim 36, 37, 54);

iii) ovine (claim 36);

iv) piscine (claim 36);

v) baboon (claim 36);

vi) murine (claim 36);

vii) porcine (claim 36); and

viii) food product (claim 40)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25-27, 31-35, 41-50, 53, and 55-65 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Additional Restriction requirement for Group I

In addition, Group I reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group, Applicants must further elect a single amino acid or nucleotide sequence.

Applicants are entitled to a pair of primers:

(SEQ ID NO: 1 and 2); or

(SEQ ID NO: 3 and 4);

and

a single probe selected from the Group:

SEQ ID NOS: 5-12.

Examination will be restricted to only the elected set of primers and a probe sequence.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive communication will contain both a proper election of a group, and a single set of primers and a probe.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a

general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
5/31/2005

YOUNG J. KIM
PATENT EXAMINER

yjk